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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,057	12/20/2000	Grant A. Krafft	97-002-L	8012

7590 02/25/2004

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,057	KRAFFT ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 5-6 in the paper filed December 10, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL. Claims 1-12 are pending, claims 1-4 and 7-12 are withdrawn from consideration, and claims 5-6 are examined on the merits.

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to methods of use for blocking amyloid β protein(s) in order to protect/treat/prevent brain cells against toxicity/Alzheimer's disease and related dementias and memory disorders. However, no compound structure, name, or peptide sequence has been distinctly claimed to which it may be surmised constitutes the "blocking" agent.

The specification does not describe the essential steps or compounds (i.e. *how* the method works) necessary to block the amyloid β proteins (i.e. assumed ADDLs). Specification page 11, ¶ 2, discuss an *assay* (of *in vitro* of B103 cells or rat hippocampal neurons, not *in vivo*) that is *useful* for identifying compounds that block the receptor binding of ADDLs to B103 cells (emphasis added). It further describes two peptides, one specifically and another generally, that may be able to block ADDLs binding (namely, peptide amyloid β 1-40 at 10 μM and generally proteins that are cleavable by brief treatment with trypsin). However, the structure (sequence) of peptide amyloid β 1-40 is not described in the specification or sequence listing, or claimed; nor are any of the supposed general proteins that are cleavable by brief treatment with trypsin (and thus a search of the invention is not possible).

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the invention, namely a method of blocking ADDLs to protect/treat/prevent brain cells against toxicity/Alzheimer's disease and related dementias and memory disorders. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112 1st Enablement

Claims 5-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for a method of blocking ADDLs to protect/treat/prevent brain cells against toxicity/Alzheimer's disease and related dementias and memory disorders, for the following reasons:

The nature of the invention: The claimed invention is discussed above.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that:

> Alzheimer's disease (AD) is the fourth most common cause of death in the U.S. after heart disease, cancer and stroke. It presently afflicts more than four million people and this number is expected to double during the next forty years as the population ages. *There is presently no cure for AD and treatments are largely palliative rather than treating the underlying causes of disease. A stated aim of the National Institute of Aging is to delay the age of onset by five years during the next five years and by ten years within the next ten years thus reducing significantly the number of people affected by AD* (Hardy (US 60108074), col. 1, lines 30-42; emphasis added).

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The specification does not describe the essential steps or compounds (i.e. *how* the method works) necessary to block the amyloid β proteins (i.e. assumed ADDLs). Specification page 11, ¶ 2, discuss an *assay* (of *in vitro* of B103 cells or rat hippocampal neurons, not *in vivo*) that is *useful* for identifying compounds that block the receptor binding of ADDLs to B103 cells (emphasis added). It further describes two peptides, one specifically and another generally, that may be able to block ADDLs binding (namely, peptide amyloid β 1-40 at 10 μM and generally proteins that are cleavable by brief treatment with trypsin). However, the structure (sequence) of peptide amyloid β 1-40 is not described in the specification or sequence listing, or claimed; nor are any of the supposed general proteins that are cleavable by brief treatment with trypsin (and thus a search of the invention is not possible).

The breadth of the claims and the quantity of experimentation needed: Given the broad range of compounds that may or may not be able to block ADDLs, and the lack of a description

of such compounds in the specification or claims, and absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art; namely it is known that blocking ADDLs will protect/treat/prevent brain cells against toxicity/Alzheimer's disease and related dementias and memory disorders, absent any compound structures or peptide sequences or tests showing that such will protect/treat/prevent brain cells against toxicity/Alzheimer's disease and related dementias and memory disorders, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112 1st Scope of Enablement

Claims 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while it *may* be enabling for treating, it does not reasonably provide enablement for preventing Alzheimer's disease and related dementias and memory disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants *may* be able to reasonably demonstrate/disclose that the claimed method is useful in treating Alzheimer's disease and related dementias and memory disorders by blocking the formation or the activity of amyloid β protein(s), and/or reducing the risk thereof. However, the claims also encompass using the method to prevent Alzheimer's disease and related dementias and memory disorders, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the

term "treat", especially with respect to preventing Alzheimer's disease and related dementias and memory disorders (which are not recognized in the medical art as being preventable conditions; see Hardy (US 60108074), as discussed above).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed method which would function to prevent Alzheimer's disease and related dementias and memory disorders.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, it is unclear what is contemplated by protecting brain cells against toxicity of amyloid β protein? No definition of what the protecting means was found in the specification. The word is vague and indefinite, and no limitations as to what does/does not constitute protection has been provided.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the amyloid β protein(s) is blocked in order to protect/treat/prevent brain cells against toxicity/Alzheimer's disease and related dementias and memory disorders. The claims are exceedingly vague and indefinite, because the methods fail to

define a complete process as to how the proteins are blocked and/or what compounds/peptide sequences are capable of blocking the proteins. Since essential steps have been omitted and no compound structure, name, or peptide sequence has been distinctly claimed to which it may be surmised constitutes the "blocking" agent, it is unclear what the invention is (or how the invention may be searched). Appropriate correction is required. Please note that no new matter may be put into the specification.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
February 21, 2004

CHRISTOPHER R. TATE
PRIMARY EXAMINER